K120914

Heraeus

JUL 25 2012

510(k) Summary

510(k) summary of safety and effectiveness information for Flexitime Fast & Scan in accordance with 21 CFR 807.92.

1. **Submitter Information**

Company Name: Heraeus Kulzer, LLC
Company Address: 300 Heraeus Way
South Bend, IN 46614

Company Phone: (574) 299-5421

Contact Person: Jamie Mearna

Date Summary prepared: December 28, 2011(Revised June 29, 2012)

2. **Device Identification**

Trade /Proprietary Name: *Flextime Fast & Scan Impression Materials* to include

- Flexitime Fast & Scan Light Flow
- Flexitime Fast & Scan Medium Flow,
- Flexitime Fast & Scan Dynamix Putty
- Flexitime Fast & Scan Easy Putty
- Flexitime Fast & Scan Dynamix Heavy Tray

Common Name: Material, Impression (21 CFR 872.3660)
Classification: Class II
FDA Code: Dental ELW

3. **Legally Market Devices to which Substantial Equivalence is claimed:**

Heraeus Kulzer, GmBH - Flexitime Impression Material (K000629)
Heraeus Kulzer, GmBH - Flexitime Fast & Scan Impression Material (K102770)

4. **Device Description**

Flexitime Fast & Scan Impression Materials are addition-cross-linking polyvinyl siloxane materials. The Flexitime Fast & Scan Impression Materials family consists of Light Flow, Medium Flow, Dynamix Putty, Easy Putty and Dynamix Heavy Tray. Flexitime Light Flow, Medium Flow, Heavy Tray are delivered in 50 ml cartridges while Flexitime Fast & Scan Dynamix Putty and Dynamix Heavy Tray are delivered in 380 ml Cartridges and Flexitime Fast & Scan Easy Putty is delivered in a 300 ml container.

The Flexitime Fast & Scan assortment is characterized by the addition of Titanium Dioxide (in order to ensure scannability) and is technically characterized by an extra-oral working time of up to 1.5 minutes and a short time in mouth of 2.0 minutes. The materials were developed to ensure hydrophilic characteristics for optimal impression

taking in the wet surroundings of the mouth combined with good mechanical properties. Also, they ensure scannability with state of the art red laser light impression scanners.

Flexitime Fast & Scan products are part of the Flexitime System.

5. **Intended Use**

Flexitime Fast & Scan is an addition-cross-linking polyvinyl siloxane impression material for all inlay, crown & bridges, endentulous and partial impressions.

The Flexitime Fast & Scan range of products are prepared without requiring additional surface treatment for optical scanning in dental scanners designed for scanning impression materials, such as the 3shape D700 laser scanners.

6. **Technological Characteristics**

The physical properties of the additional Flexitime Fast& Scan assortments: Dynamix Heavy Tray and Easy Putty are like Flexitime Fast and Scan (K102770) and Flexitime (K000629) products in the fact that they are also in compliance with ISO 4823.

The new assortment of Flextime Fast and Scan materials (like the original Flexitime Fast & Scan K102770) can be prepared without requiring additional surface treatment for optical scanning in dental scanners designed for scanning impression materials.

7. **Nonclinical Testing**

In accordance with US FDA Medical Device Regulations, any medical device is required to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with FDA recognized standard, EN ISO 10993-1.

The biological compatibility of Flexitime Fast & Scan was verified in accordance with the international standards.

The biocompatibility of Flexitime Fast & Scan in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk relation has been judged as positive.

8. **Clinical Testing**

In accordance with US FDA Medical Device Regulations, any medical device is required to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation, which is intended to critically evaluate the clinical benefits of the medical device in comparison to tis potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to FDA recognized standard, EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

Considering the evaluated scientific data and technical results for Flextime Fast & Scan it is concluded that the products can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and accepted, when weighed against their benefit to dentistry. Therefore, a positive benefit versus risk ratio can be stated by the experts for Flexitime Fast & Scan assortment, provided that the products are applied in accordance with the intended use as outlined in the manufacturer's instructions for use.

9. Summary of Conclusion

The new Flexitime Fast & Scan assortment is substantially equivalent to the original Flexitime Fast & Scan and Flexitime. All of the products are indicated for taking impression materials of suited techniques. In addition, the new assortment of Flexitime Fast & Scan is scannable without prior powdering as is required with the predicate device, Flexitime Fast and Scan.

A biocompatibility evaluation has been performed by a toxicologist for Flextime Fast & Scan, and it was confirmed that the product meets the requirements of FDA recognized standard, ISO 10993 Standard and it was concluded that the safety of Flexitime Fast & Scan is equivalent to that of the predicate device.

The risk analysis was carried out for Flexitime Fast & Scan and it was concluded that the safety of the Flexitime Fast & Scan device, for the intended use, is substantially equivalent to the predicate device. Flexitime Fast & Scan and the predicate device both have the same indications for use, warnings and contraindications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Mr. Jamie Mearna
Quality Assurance & Regulatory Associate
Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

Re: K120914
Trade/Device Name: Flexitime Fast & Scan
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 09, 2012
Received: July 11, 2012

Dear Mr. Mearna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K126914

Device Name: **Flexitime Fast & Scan**

Indications for Use:

Flexitime Fast & Scan is an addition-cross-linking polyvinyl siloxane impression material for all inlay, crown and bridges, endentulous and partial impression.

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K126914